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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,268	03/04/2002	Robert Wyckoff	2001-8050-RA	4134

30184 7590 12/02/2004

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EXAMINER

RAGONESE, ANDREA M

ART UNIT PAPER NUMBER

3743

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,268

Applicant(s)

WYCKOFF, ROBERT

Examiner

Andrea M. Ragonese

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 March 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/22/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Invention I, **claims 1-20**, in the reply filed on September 13, 2004 is acknowledged. The traversal is on the ground(s) that "Claims 21-24 cannot be practiced by another different apparatus, nor can the apparatus, an air pathway clearance devices, as claimed, be used to practice another materially different process." This is not found persuasive because the Examiner still believes that the apparatus as independently claimed can practice another and materially different process in which negative pressure is not created, instead the user is merely wearing the apparatus in the off position. Therefore, the requirement is still deemed proper and is made **FINAL**.

2. **Claims 21-24** are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 13, 2004.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the buckle of **claim 6**, the snap of **claim 7**, the clasp of **claim 8**, the magnet of **claim 9**, the electronic data collection instrumentation of **claim 15** and the linked segments of **claim 16** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

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4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures.

5. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The disclosure is objected to because Applicant has used 35 U.S.C. 112, sixth paragraph, means-plus-function language to define features of the claimed invention. Accordingly, Examiner requires Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to *explicitly* state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. This requirement can be made "[even] if the disclosure

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implicitly sets forth the structure, materials, or acts corresponding to the means- (or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs.” See MPEP § 2181. See *B. Braun Medical*, 124 F.3d at 1424, 43 USPQ2d at 1900; *Wolfensperger*, 302 F.2d at 955, 133 USPQ at 542. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **Claims 1-16** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to set forth the supporting structure, material or acts corresponding to means- (or step-) plus-function and distinctly claim the subject matter which applicant regards as the invention. Although 35 U.S.C. 112, sixth paragraph, statutorily provides that one may use means-plus-function language in a claim, one is still subject to the requirement that a claim particularly point out and distinctly claim the invention. Therefore, if one employs means-plus-function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by 35 U.S.C. 112, second paragraph. See *In re Donaldson Co.*, 16 F.3d at 1195, 29 USPQ2d at 1850; *Knowlton*, 481 F.2d at 1366, 178 USPQ at 493.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **Claims 1-5 and 10-11** are rejected under 35 U.S.C. 102(b) as being anticipated by Wirtz (US 4,657,003). Wirtz discloses device **82** for wear on the neck of a user which is fully capable of maintaining air pathway clearance (column 8, line 58 through column 9, line 37), as shown in Figures 12-14, comprising:

- a support member **84**, said support member **84** having an inner surface, an outer surface and a peripheral edge;
- securing means **88**, said securing means **88** carried by said support member **84** and said securing means **88** enabling retention of said support member on the neck of the user;
- retention means **89**, said retention means **89** enabling retention of said securing means **88** relative to said support member **84**;
- sealing means **94**, said sealing means **94** carried by said support member **84** proximate to said inner surface of said support member **84**, said sealing means **94** enabling substantially airtight positioning of said support member **84** against the neck of the user, and said sealing means **94** generally protruding from said inner surface of said support member **84**, thereby

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defining an air compartment between said support member **84** and the neck of the user;

- at least one valve **25**, said valve **25** carried by said support member **84**, wherein said valve **25** enables the exit of air from said air compartment.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. **Claims 6-9 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wirtz (US 4,657,003), as applied to **claim 1** above, in view of Calabrese (US 4,886,052). Wirtz teaches an apparatus comprising all limitations recited in **claims 6-9 and 16**, but does not expressly disclose that the securing means includes both a strap and another attachment mechanism selected from the group consisting of a buckle, a snap, a clasp and a magnet or that the support member is formed of a plurality of linked segments. At the time of the invention was made, all of these types of attachment

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mechanisms for linking together more than one support member segment were very well known in the art and prevalently used. Specifically, Calabrese teaches that “a strap fastener...prevents further expansion of slit **35**, and firmly secures front collar half **12**’ to the contour of the patient’s neck” (column 9, lines 39-54). However, Calabrese also teaches that “[those] skilled in the art will clearly recognize that any suitable fastening means such as an adjustable buckle, snaps or the like, can be utilized to perform the function” (column 9, lines 54-57). Buckles, snaps, clasps and magnets are all equivalents in the field of securement. Therefore, it would have been obvious to one having ordinary skill in the art to use any one of these securement means as Applicant has done to firmly secure more than one support member segment together. Moreover, Applicant has not asserted that the specific securement means or the plurality of linked segments recited provides a particular advantage, solves a stated problem or serves a purpose different from that of a hook and loop fastener assembly attaching together two ends of a one-piece construction support member, thus the use of any other type of securement means or a multiple segmented support member lacks criticality in its utilization and design. One of ordinary skill in the art, furthermore, would have expected Applicant’s invention to perform equally well with any type of adjustable attachment mechanism that is capable of opening/sealing and closing/resealing a support member, whether it is constructed of one segment or more than one segment, around a patient’s neck. Therefore, it would have been obvious to modify the apparatus of Wirtz by altering the securing means to be any one selected from the group of buckles, snaps, clasps and magnets and to secure more than one support member segment together

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because it is well known in the art to use these types of securing means in order to secure the multiple segments of a support apparatus to the neck of a patient.

14. **Claims 12, 17-18 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wirtz (US 4,657,003), as applied to **claim 1** above, in view of Visness et al. (US 6,494,854 B1). Wirtz discloses an apparatus comprising all the limitations recited in **claims 12, 17-18 and 20**, with the exception of a gasket. However, the use of gasket was known at the time the invention was made. Specifically, Visness et al. teaches the use of gasket **100** "to disperse and cushion the weight of the device **30** as well as the resultant head and neck forces of the patient on the device **30**" (column 6, lines 12-38). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Wirtz by adding a gasket underneath the support member because it is well known in the art, as taught by Visness et al., to use a gasket in order to make wearing the device more comfortable for the patient.

15. **Claims 13-15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wirtz (US 4,657,003), as applied to **claim 1** above, in view of Sackner (US 4,452,252). Wirtz discloses an apparatus comprising all the limitations recited in **claims 13-15**, with the exception of a data collection port and means for measuring performance. However, the use of a data collection port and means for measuring performance was known at the time the invention was made. Specifically, Sackner teaches the use of device with a data collection port for analyzing "specific pulmonary events, such as snoring, coughing, apneas, swallows, etc." (column 2, line 60 through column 3, line 9).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Wirtz by adding a measurement device with a data collection port because it is well known in the art, as taught by Sackner, to use such a device for monitoring a patient's vital signs in order to measure the performance of an apparatus.

16. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wirtz (US 4,657,003) in view of Visness et al. (US 6,494,854 B1), as applied to **claim 18** above, and further in view of Sackner (US 4,452,252). Wirtz discloses an apparatus comprising all the limitations recited in **claim 19**, with the exception of a data collection port. However, the use of a data collection port was known at the time the invention was made. Specifically, Sackner teaches the use of device with a data collection port for analyzing "specific pulmonary events, such as snoring, coughing, apneas, swallows, etc." (column 2, line 60 through column 3, line 9). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Wirtz by adding a measurement device with a data collection port because it is well known in the art, as taught by Sackner, to use such a device for monitoring a patient's vital signs in order to measure the performance of an apparatus.


Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **571-272-4804**. The examiner can normally be reached on Monday through Thursday from 8:30 am until 4:30 pm.

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18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR 
November 29, 2004


Henry Bennett
Supervisory Patent Examiner
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